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A Message from the Director

Gene R. Haislip, Director
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This issue of Registrant Facts deals with several new and important developments in terms of both drug abuse problems and the techniques for dealing with them. Certainly one of the major new sources of drugs now available in the illicit traffic in the United States is the result of diversion from international commerce. This is a matter in which DEA, and the Office of Compliance and Regulatory Affairs in particular, has provided and must provide the leadership. However, I would like to call particular attention to a new problem in drug abuse in which others must share heavily in the responsibility if results are to be achieved. This is the problem of so-called "look-alike" drugs.

We see a unique situation developing in which unethical entrepreneurs are profiteering by using loopholes in society's legal and regulatory apparatus to peddle drugs and the concept of drug abuse to the nation's youth. Of course, these drugs are not controlled substances but the message which their sales and advertising conveys is unmistakable: that drugs should be used for thrills and not solely for legitimate medical reasons.

Teen-agers who begin with the abuse of "look-alikes" may soon be abusing controlled drugs. Teenagers who begin making profit by distributing handfuls of "look-alikes" in school corridors may soon be selling controlled drugs to their friends. The so-called "look-alikes" seem consciously designed to serve the function of a sort of kindergarten for illicit traffic and abuse. The drugs themselves can be hazardous even though they may be safe in legitimate preparations when used for legitimate reasons. This is due to the fact that the abusers of "look-alikes" may consume large doses in an effort to achieve effects similar to controlled substances.

The Federal Government does have authority which can be brought to bear. In particular, both the Food and Drug Administration and the United States Postal Service deserve special commendation for the vigorous actions which they have pursued under their own statutes. Nevertheless, much of the burden of responding is going to fall on the states and localities.

DEA has designed a model state act for this very purpose. But if local action is to be taken, and is to be effective, it will largely be because the major professions have taken the leadership to advise their state authorities. This is the task which DEA is urging upon all registrant groups. No health professional can approve of what is happening. No legitimate drug firm wants to see its industry associated with this kind of sleazy, destructive enterprise. This is, therefore, a new challenge which provides the opportunity for new private leadership in the service of the public. □

International Drug Diversion

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In addition to the diversion of controlled substances in the United States by a variety of methods, the trafficking of foreign-produced pharmaceuticals is a major problem affecting this country.

Many large manufacturers of pharmaceuticals are located in other nations where regulatory controls are often quite different from those of the United States. Several drugs which are tightly controlled in the United States have not been considered a problem in other countries and therefore have not been or have only recently been controlled. These conditions afford drug traffickers opportunities for diversion.

The problem is best exemplified by the example of methaqualone (commonly referred to by its United States trade name Quaalude®), which during the 1970's experienced tremendous growth in abuse. As a result of strict United States controls placed on methaqualone, traffickers looked outside of the United States in order to obtain large supplies of the drug. In 1977 it became apparent that clandestine methaqualone tableting laboratories in Latin American countries were being established. Since most European countries did not control the importation or ex-

INTERNATIONAL, *see p.2*

INTERNATIONAL, *from p. 1*

portation of methaqualone, these violators found a new source of supply, select European pharmaceutical suppliers that apparently did not verify the legitimacy of their customers. Illicit traffickers in Latin American countries ordered methaqualone powder from one of a number of European firms and retained their anonymity by using a series of brokers. Since the drug has not been controlled in many countries, *"legitimate"* shipments of methaqualone powder have been shipped for unlawful conversion into tablets. The tablets are then smuggled into the United States, usually, by small privately owned aircraft.

During 1980, 12.6 tons of methaqualone were seized by law enforcement authorities in the United States and in South America. In the first ten months of 1981, investigative efforts have resulted in the seizure of over 51 tons.

Projections for 1980 indicated that at least 100 tons of legitimately produced methaqualone powder were diverted into the illicit market, primarily to Colombia, for tableting into dosage forms. The extent of the diversion problem can be appreciated when these seizure figures are compared to the annual legitimate sales of methaqualone for the United States of only 4.2 tons. Methaqualone is not the only drug which appears in this international pattern of diversion. Since 1976, over 1,400 kilograms of secobarbital, 1,300 kilograms of methamphetamine and large quantities of other stimulants have been diverted into illicit channels of distribution.

The diversion of drugs under minimal international control may pose equally alarming consequences. It appears that the greater the extent of a drug's availability to the legitimate market, the more likely will be its diversion and unpredictable applications. For example, approximately 3 billion dosage units of diazepam are prescribed annually in the United States. The legitimate drug product is tableted in 2 mg., 5 mg. and 10 mg. doses. However, bulk diazepam has been found to be diverted from legal channels and reformulated in clandestine laboratories into tablets that contain far more diazepam than the medicinally recommended dose. The most consistently recurring form of clandestine diazepam between 1977 and 1981 has been methaqualone counterfeits. Evidence of its being sold as methaqualone is its resemblance to Quaalude®. Since 1980, the counterfeits bear the inscription of the recent United States manufacturer of methaqualone. Their average dose is 36.7 mg. per tablet and contains as much as 290.0 mg. of diazepam. These methaqualone *"look-alikes"* have been found in all sections of the United States as well as Colombia, Turkey, and Canada.

Gene R. Haislip (second from left), Director, Office of Compliance and Regulatory Affairs, discusses international diversion of methaqualone from foreign sources with members of his staff. Shown with Mr. Haislip are Ronald Buzzeo (left) Chief, Compliance Division, Michael Moy, Staff Assistant, and Mitzy Williams, Compliance Analyst.

Through diplomatic initiatives with major European pharmaceutical-producing countries, the DEA has had a significant impact in reducing the availability of methaqualone. Three countries which had been supplying large quantities of bulk powder have voluntarily ceased or limited production in an effort to reduce methaqualone trafficking. DEA will continue to solicit cooperation from regulatory and enforcement personnel overseas to reduce the supply and availability of dangerous drugs that are affecting the United States.

The DEA is also working with the United Nations and foreign governments throughout the world to attack this diversion problem. The introduction and passage of stringent individual country laws over the importation and exportation of these drugs of abuse is encouraged. □

Controlled Substance Look-Alikes

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The manufacture, distribution, and use of so-called controlled substance look-alike drug products have reached alarming proportions in the past year. Parents, educators, government officials, health authorities, and law enforcement personnel are deeply concerned over this novel and contemptible facet of the drug abuse problem. In October 1981, both the House Judiciary Subcommittee on Crime and the House Select Committee on Narcotic Abuse and Control considered the look-alike problem serious enough to hold hearings. The following is a description of the look-alike problem, its dangers and what has been and can be done to curb and eliminate this phenomenon.

Definition

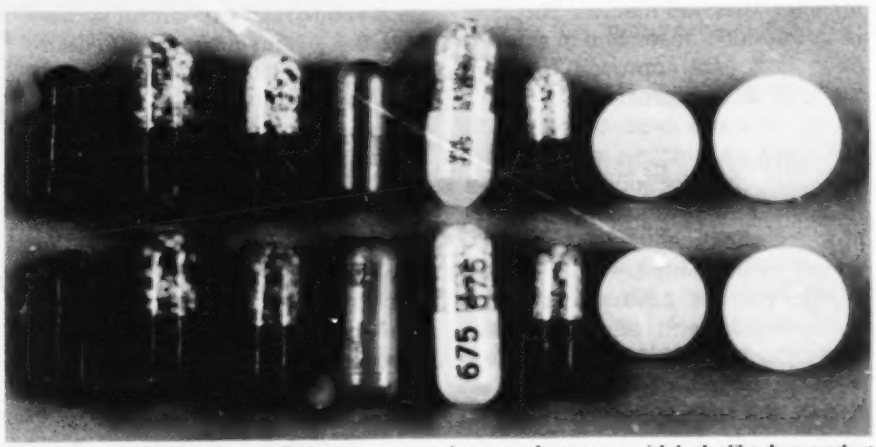
Look-alikes are tablets and capsules containing noncontrolled, over-the-counter ingredients, but which are manufactured to closely resemble well-known, highly abused controlled drug products. Although manufacturers properly label containers of look-alikes, there is an obvious intent to misrepresent the look-alikes as controlled substances even at this level. For example, manufacturers are producing black capsules marked 18-985 or 18-845 (compared to the legitimate 18-875 Biphetamine®) and pink tablets marked BT72 (compared to a legitimate BI62 Preludin®) and advertising them as *"effective stimulants"* and *"highly profitable."* When sold on the street, look-alikes are removed from their original containers and passed as controlled drugs via slang terms such as *"speed," "bam," "black beauties,"* etc.

Profits

The profits realized from the sale of look-alikes make this an attractive endeavor for the unscrupulous entrepreneur. Prices from distributors range from $19 to $150 per 1,000 pills which can be sold for $.50 to $1.50 per pill on the street, a profit of $1,000-$1,500 for each 1,000 capsules sold. It is estimated that during the period January 1981 to June 1981, roughly 30 million dosage units of look-alikes were manufactured each week. DEA is aware of 10 manufacturers and approximately 150 distributors of look-alikes.

One of the most unfortunate aspects of the look-alike phenomenon is the exploitation of college, high school, and even junior high school aged students. Large-scale advertising campaigns utilizing color brochures, magazine and newspaper ads, highway billboards, and flyers have been mounted by look-alike distributors and are aimed primarily at teenagers and young adults. Look-alikes are advertised as body stimulants, energizers, or sleep-aids, *"a safe, legal way to get high."* Distribution of business cards, flyers, and other promotional materials is common at rock concerts, athletic events and on college campuses and advertising material is sent through the mail to private residences. A flyer mailed to college campuses had the following wording on the envelope:

LOOK-ALIKES, *see p.4*



Representative samples of controlled substances are shown on the top row with look-alike drug products shown on the bottom row.

LOOK-ALIKES, *from p.3*

"TO COLLEGE MAIL HANDLERS, please deliver to dorms that have a high proportion of drug users. We request that this letter be delivered to an individual that needs or uses drugs so he may be given direction and shown the way."

Public Health Problems

The look-alikes mimic the appearance of popular stimulant products such as Biphetamine®, Ionamin®, Dexamyl®, Dexedrine®, Eskatrol®, Preludin® and Fastin® or depressants such as Valium®, Librium® and Quaalude®. They generally contain the following over-the-counter ingredients: caffeine, ephedrine, pseudoephedrine, phenylpropanolamine, acetaminophen, salicylamide, doxylamine, and chlorpheniramine, either individually or in combination. When taken for their intended medical purpose, in therapeutic doses and in accordance with FDA-approved labeling, the look-alike ingredients are generally safe and produce only mild stimulant or sedative side effects. However, the look-alike user is led to believe that these *"pills"* will produce effects equal to those produced by the controlled drugs they mimic. Serious adverse reactions are possible and have occurred when the look-alikes are ingested in large quantities in an effort to obtain the desired effect. These reactions may range from nervousness, insomnia or drowsiness to sharp rises in blood pressure, cerebral hemorrhage and temporary psychotic episodes. Emergency rooms are reporting an increasing number of individuals seeking emergency medical treatment associated with the use of the ingredients found in look-alikes. A number of deaths associated with look-alike use have been reported with caffeine intoxication as the likely cause of death.

The risk of serious drug overdose from controlled substances is greatly increased for look-alike users who unknowingly take equal amounts of the controlled drug. This is particularly true when depressants are involved. Further, health care professionals in emergency rooms, poison control centers and drug abuse clinics are hampered in providing proper medical care in overdose cases due to the misrepresentation of the look-alikes to the user.

Nonmedical Probems

The dangers of the proliferation of look-alikes are not limited to direct effects on the public health. Law enforcement personnel have expended much time, money, and manpower buying or seizing *"pills"* only to discover, upon chemical analysis, that no controlled substance is present and no prosecutable crime has been committed. Consequently, police in some jurisdictions have stopped buying or seizing *"pills,"* thus making it easier for drug dealers to sell the real controlled substance. This undermines public support for the police since citizens believe that a large drug problem is being ignored. Perhaps worst of all, the unabated advertising of look-alikes as *"100% legal"* gives the impression of societal acceptance of the use of drugs for recreational purposes. This counteracts the efforts of the many drug abuse educational programs supported by government and public organizations. Look-alikes, like drug paraphernalia, clearly have become part of the drug abuse problem in this country.

DEA's Six-Point Program

The look-alike problem must be attacked at all levels of government, by industry, and by parent and community groups. Efforts directed at this problem, however, must take into consideration the facts that the look-alike ingredients have legitimate medical uses, that they are found in many of the more common over-the-counter products, and that when used as directed are generally not harmful. DEA, under the Controlled Substances Act, has no jurisdiction over these look-alikes since only noncontrolled substances are involved. However, DEA considers the look-alike phenomenon to be

a facet of drug abuse and has undertaken a six-point program aimed at eliminating this problem. Briefly, the six points are:

1. Drafting of a model act for state governments to adopt;
2. Preparation of supporting documentation describing the problem, its hazards and other educational information, to be used by local governments and community groups;
3. Fostering intergovernmental agency cooperation and providing active support to other agency efforts;
4. Enlisting the support and/or appropriate action of the legitimate pharmaceutical industry;
5. Educating and encouraging the support of parent and community groups through the publicizing of this DEA initiative; and
6. Targeting of states with heavy concentrations of look-alike manufacturers or distributors to encourage legislative action.

DEA Model Look-Alike Act

At the heart of DEA's intiative is the Model Imitation Controlled Substances Act which is targeted to eliminate these undesirable look-alike enterprises through the application of regulations and civil and criminal penalties. The Model Act amends applicable state Controlled Substances Acts by incorporating by reference certain definitions. The term *"imitation controlled substance"* is the key to the Model Act. It is defined as a non-controlled substance which by dosage unit appearance or representation made would lead one to believe that the substance is a controlled substance. The Model Act would make it unlawful for any person to manufacture, distribute, possess, use or advertise imitation controlled substances. It is patterned after DEA's Model Drug Paraphernalia Act, drafted in 1979. The DEA Model Act will serve as a guide for states that wish to take legislative action against look-alike manufacturers and distributors. At least twelve states have independently enacted or are considering legislation against look-alike enterprises. These states include: Arkansas, Colorado, Connecticut, Delaware, Florida, Indiana, Kansas, Louisiana, Maryland, North Carolina, Oklahoma, Oregon, and South Dakota. The DEA Model Act will help to provide some uniformity in future state legislation.

Other Government Efforts

DEA has enlisted the support of one of the largest manufacturers of hard gelatin capsules. This manufacturer will not fill orders for capsules for suspected look-alike manufacturers without proof that they will not be used for look-alikes. Other capsule manufacturers have indicated a similar willingness to cooperate.

Other Federal agencies have taken action against the look-alike manufacturers and distributors with some success. The U.S. Postal Service has filed over 39 complaints in nine states citing postal code violations involving look-alike drugs. An additional 40 distributors are under investigation. If the complaints are upheld, the U.S. Postal Service would be able to withhold and return mail addressed to these distributors who solicit money by false representation. To date, the U.S. Postal Service has obtained **Consent Agreements** from nine distributors and **False Representation Orders** against nine others.

On September 30, 1981, the Food and Drug Administration, after lengthy investigations, took seizure actions against nine look-alike manufacturers. These seizures were based on violations of the labeling and counterfeiting statutes of the Food, Drug, and Cosmetic Act. Complaints were filed in six jurisdictions and the seizures were made by U.S. Marshals accompanied by FDA personnel. The seizures netted 15 million filled capsules, 800,000 tablets, and 20 million empty capsules. Machinery used in the manufacture of counterfeits which included punches, dies, imprinters and presses was also seized.

Joint Effort Needed

The actions taken by the U.S. Postal Service, FDA, and DEA will hopefully have a substantial deterrent effect on the problem of look-alike trafficking. The tremendous profits attendant to the sale of drugs for recreation and the ingenuity of those involved in these enterprises will make it difficult to eradicate this problem completely. A continuous and concerted effort at all levels of government, in addition to industry, community, and family support, is necessary to minimize the problem of look-alike drugs. □

Utilization of ARCOS as a Primary Resource to Detect Diversion of Controlled Substances.

Recent Application of Computer Software Technology

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ARCOS stands for **Automation of Reports and Consolidated Orders System.** It is a system which provides for the audit of drug inventory transactions which are originated by manufacturers, distributors, importers and exporters of certain controlled substances. These substances are those in Schedules I and II along with narcotic substances in Schedule III. Manufacturers must also report on narcotic substances used for Schedule V products. As of October 1981, there were 1,379 distributors and 382 manufacturers registered to handle controlled substances, most of whom are required to report to DEA on a periodic basis. The reportable transactions consist of sales and purchases as well as other activities which will add to inventory, or subtract from inventory, of selected controlled substances from point of import or manufacture to point of sale, distribution, export, or other disposition to the dispensing level.

ARCOS is utilized not only to monitor the distribution of certain controlled substances in the U.S., but also can be utilized to support studies of the diversion of these controlled substances. The way in which it is utilized is dependent upon the manner in which a study becomes initiated. Different manners include: a sample of tablets or capsules may be confiscated in a seizure and ARCOS will be utilized to determine the amount of controlled substances being shipped to the area where confiscation occurred, along with the ordering patterns of selected pharmacies, hospitals or practitioners in the area; an informant may relay to a Federal investigator that there are sizable amounts of barbiturates in the drug subculture or that a particular practitioner is known in the subculture as a *"pill pusher"* or *"script writer,"* and ARCOS will be utilized to show the amount of barbiturates distributed to the area or to pharmacies at which the practitioner's patients might be cashing prescription orders; a printout of **Drug Abuse Warning Network (DAWN)** information may show that there is a rising problem with certain drugs in a particular **Standard Metropolitan Statistical Area (SMSA)** or county within the SMSA, and ARCOS would be utilized to determine distribution patterns of certain controlled substances within the SMSA or county; or a printout from ARCOS may show that sizable amounts of certain controlled substances have been ordered by identifiable pharmacies in a particular community which may require further investigation.

In three of the four examples above, ARCOS was used in support of an investigation which was initiated by another source. However, the fourth example shows that ARCOS itself can serve as the point of origin for an investigation. This article describes the methodology of an ongoing nationwide study in which ARCOS data is fed into computer software programs in order to identify possible diversion of controlled substances in the U.S. Schedule II drugs are highly abusable and very likely candidates for being diverted from legitimate drug distribution channels for illicit use.

All things being equal there is the greatest potential for diversion to occur where greater amounts of controlled drugs are available. **Figure 1** is a graph produced by the computer which shows the absolute distribution of phenmetrazine in the U.S. in calendar year 1980. The *"mountains"* which are produced by this graphics procedure are scaled relative to the amount of phenmetrazine distributed to each state. As seen, there are eight states which stand out relative to other states. These are: California, Michigan, Texas, Pennsylvania, Ohio, Florida, Louisiana, and New York.

The absolute amount of a drug distributed to a state in one year can also be compared to the amount distributed to the state in a prior year to determine whether there was an increase/decrease, and this change for each state can

U.S. Department of Justice
Drug Enforcement Administration

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Model Imitation Controlled Substances Act

Drafted by the
Drug Enforcement Administration
of the
United States Department of Justice

October, 1981
With Comment

Section 1. Definitions

a. The term "controlled substance" means a substance as defined in (insert appropriate citation for definition of "controlled substance" in State Controlled Substances Act).

b. The term "distribute" means the actual, constructive, or attempted transfer, delivery, or dispensing to another of an imitation controlled substance.

c. The term "manufacture" means the production, preparation, compounding, processing, encapsulating, tableting packaging, or repackaging, labeling, or relabeling, of an imitation controlled substance.

d. The term "imitation controlled substance" means a substance that is not a controlled substance, which by overall dosage unit appearance (including color, shape, size and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. Nothing in this Act shall apply to a noncontrolled substance that was initially introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate. In those rare cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as

related to "representations made" in determining whether the substance is an "imitation controlled substance":

(1) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(2) Statements made to the recipient that the substance may be resold at a price substantially higher than the usual and customary price for the substance.

(3) Whether the substance is packaged in a manner normally used for illicit controlled substances.

(4) Evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities.

(5) Prior convictions, if any, of an owner, or anyone in control of the object, under state or Federal law related to controlled substances or fraud.

(6) The proximity of the substances to controlled substances.

Section 2. Offenses

a. *Manufacture or distribution*—It is unlawful for any person to manufacture, distribute, or possess with intent to distribute, an imitation controlled substance. Any person who violates this section shall be guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

b. *Distribution to a minor*—Any person 18 years of age or over who violates Section 2a by distributing an imitation controlled substance to a person under 18 years of age is guilty of an aggravated crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

c. *Possession*—It is unlawful for any person to use, or to possess with intent to use, an imitation controlled substance. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

d. *Advertisement*—It is unlawful for any person to place any newspaper, magazine, handbill or other publication, or to post or distribute in any public place, any advertisement or solicitation with reasonable knowledge that the purpose of the advertisement or solicitation is to promote the distribution of imitation controlled substances. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

e. *Immunity*—No civil or criminal liability shall be imposed by virtue of this Act on any person registered under the Controlled Substances Act who manufactures, distributes, or possesses an imitation controlled substance for use as a placebo by a registered practitioner in the course of professional practice or research.

Section 3. Forfeiture

(Insert designation of state civil forfeiture section) is amended to provide for the civil forfeiture of imitation controlled substances by adding the following after paragraph (insert designation of last category of forfeitable property):

"( ) all imitation controlled substances as defined by (list appropriate citation for this Act in the state's statutes).

Section 4. Severability

If any provision of this Act or the application of the Act to any person or circumstance is held invalid, the invalidity does not affect the other provisions or applications of the Act which can be given effect without the invalid provision or application and to this end the provisions of this Act are severable.

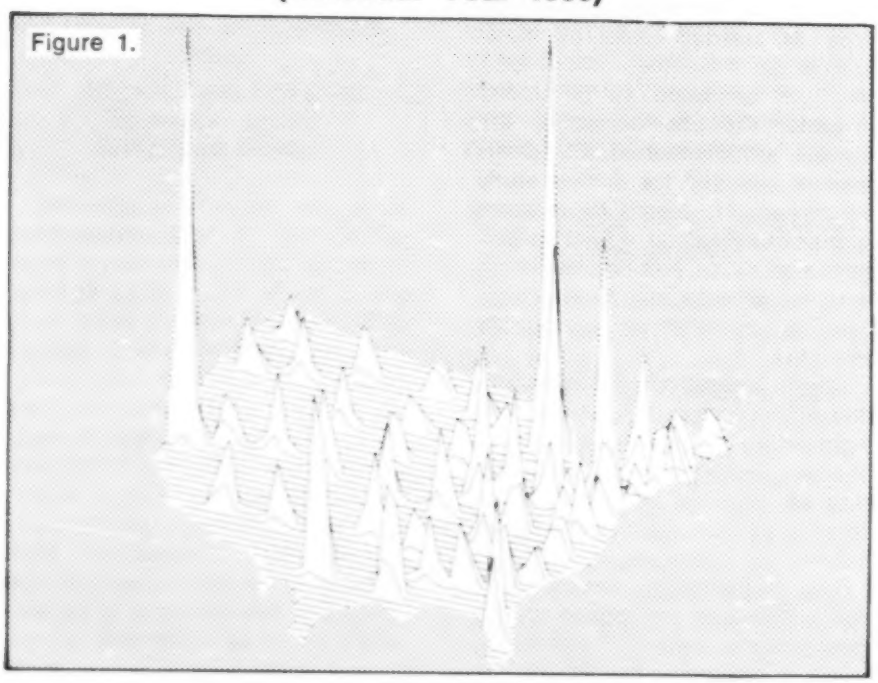
Comment

The Model Imitation Controlled Substances Act incorporates by reference certain definitions in the applicable State Controlled Substances Act, but does not attempt to incorporate or amend the definition of *"counterfeit substance"* in the State Controlled Substances Act. DEA believes it would unnecessarily confuse the issues to attempt to amend the definition of *"counterfeit substance"* in the State Controlled Substances Act. Therefore, the Model Act uses a new term of *"imitation controlled substance"* as the key to the Model Act.

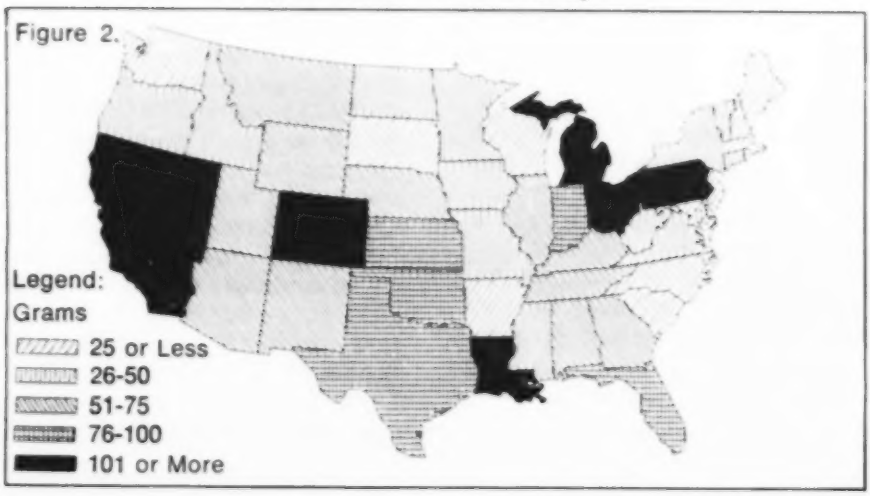
DEA believes that many of the existing and draft State Acts which have sought to reach the look-alike problems have placed too much emphasis on the representations made by the seller of the substances. Hence, the DEA Model Act seeks to place emphasis on the *"look-alike"* nature of most of the substances involved to sustain the burden of proving a violation. The portion of the DEA Model Act which deals with *"representations made"* by the seller is not really intended to reach look-alikes in tablet or capsule form, but rather, is intended to reach those cases where powder or liquid is represented to be controlled substances. Most cases related to powder will involve alleged cocaine or heroin and most cases related to liquid will involve alleged PCP or other hallucinogenic drugs.

The sections of the Model Act which deal with penalties, advertisement, forfeiture, and severability are framed from the pattern used in the Model Drug Paraphernalia Act, drafted by DEA in August 1979. As of October 1981, the Model Paraphernalia Act has been enacted by 23 states and many localities, and has been upheld at the state level by every Federal District Court and Appeals Court that has considered it. As in the Model Paraphernalia Act, the Model Imitation Controlled Substances Act leaves to each state the specific penalty to be inserted as a sanction for each of the criminal offenses proscribed by the Act.

Phenmetrazine Distribution in the U.S. (Calendar Year 1980)



Phenmetrazine Distribution in the U.S. Grams per 10,000 Population (Calendar Year 1980)



Source: DEA ARCOS System

be compared with the U.S. as a whole. In the absence of further information or additional technology, states in which there was not only a large amount of a drug received but which also had a much greater increase in the amount received in a subsequent year, compared to the U.S., might be targeted for study concerning possible diversion.

Further information and additional technology are available, however, which turn the methodology for investigating possible diversion from one involving the absolute amount to one involving the relative amount of the drug distributed. This means that the total resident population of a state is taken into account. Thus, the amount of the drug distributed to a state is taken relative to the population of the state. States can then be ranked according to the amount of a drug received per 10,000 population and can be compared to the U.S. rate. **Figure 2,** also produced by the computer, shows the rate in the amount of phenmetrazine distributed to a state per 10,000 population. As seen, California, Nevada, Colorado, Louisiana, Michigan, Ohio and Pennsylvania each received at least 101 grams of phenmetrazine per 10,000 population in calendar year 1980, if not more.

That there is some relationship between population of a state and the amount of a drug distributed to the state can be shown statistically. There remain, however, other factors affecting the amount of a specific drug distributed such as age distribution of the population, practices and habits taught by medical schools within the state, state laws and regulations, etc. Nonetheless, the factors of population size and

amount of a drug received can be input into a mathematical equation which, when run on the computer, results in a plot showing which states are receiving an excessive amount of that drug given the size of population and the specifics of the equation. An approximate excessive amount that the states received is also shown.

Once states have been selected for further investigation, the methods described above can be applied to 3-digit zip code areas within the states. The 1970 zip code census tapes have been programmed in order to obtain not only the size of population within the 3-digit zip code areas, but also other information about the population such as income, size of family, racial makeup, age, sex, work status of the population, etc. Zip code areas which stand out relatively high when these methods are applied are selected for more study. This entails inserting into a computer program data for each pharmacy in the zip code area on the amount of the drug ordered in the previous year. These data are then manipulated by the computer to produce a number of statistics which describe the ordering practices of pharmacies in the zip code area, along with plots which show these practices.

Using this information, it is possible to compare any individual pharmacy to the group of pharmacies as a whole for the zip code area. Individual pharmacies may be selected for further study if they ordered an extensive amount of a drug, or greatly increased the amount of drug ordered from previous years. Once pharmacies are selected for further study, two actions may occur: (1) a printout may be requested showing the precise ordering habits of a pharmacy for the past several years in terms of the quantity of drugs ordered by type of dosage unit, by date, and/or (2) case files within DEA may be searched to determine if either the pharmacies or the owners are mentioned. For pharmacies selected for further study which would seem to warrant further investigation, a field investigation of these pharmacies could then be ordered which would include a review of all appropriate records.

Where warranted, the investigation will be carried further, perhaps culminating in the arrest of a practitioner and/or pharmacist who may be involved in diverting the target drug from legitimate medical distribution channels.

The methodology described in this article can be applied to targeting of any controlled substance which is reportable to ARCOS.

In conclusion, it is noted that it is important to know why certain states received greater amounts of a drug than other states even when population size is taken into consideration. There has been little study to date on differing ordering practices within states which would help to explain this. From the standpoint of proper drug utilization, it may well be that certain state, or county, medical boards need to take a more active role in determining not only who the practitioners are that may be involved in diverting drugs, but also those that are involved in overprescribing. □

Some Voluntary Compliance Programs Aimed at Self-Regulation

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Self-regulation is not new to the professions. After all, the professions pride themselves on adherence to strict codes of ethics and their peer review systems. This article discusses some voluntary efforts and activities initiated by various professional groups to regulate themselves. Certainly, it is activities like those presented here that do much to establish peer pressure and self-regulation and state involvement. Although this article does not contain an exhaustive list of activities and programs, it does discuss some of the major ones.

Professional Integrity

The Drug Enforcement Administration respects the professional integrity of its registrants and recognizes that it can serve the public interest by working together with registrants to develop acceptable and cooperative programs. Consequently, because professionals generally comply with the law and also because they have their own self-control programs, DEA is able to concentrate its resources on the more serious problems of illicit drug marketing, smuggling, drug trafficking, and the like. To support the philosophy of self-regulation, it is important that the professions recognize that unethical and irresponsible individuals have no place among them. In the long run, self-regulation can be an effective and constructive type of enforcement.

Triplicate Prescription Programs

Several states have found that a triplicate prescription requirement provides a useful mechanism to control or curtail forged prescriptions and reduce overprescribing. Under such a system, the state government issues to licensed physicians special prescription blanks to be used for prescribing designated controlled substances.

The blanks are serially numbered and the physician is held accountable for those issued to him. These blanks combine an original and two carbons. The physician retains a copy and gives two to the patient. The patient presents the prescription order (two copies) to the pharmacist for dispensing. The pharmacist dispenses the prescription medication and retains the original prescription order and the copy is forwarded to the state for review.

Some items that an efficient and well-run triplicate prescription system probably should contain include: (1) the prescription blank should have the physician's name, address, and CSA registration number printed by the state at the time of issuance, (2) prescription blanks should be serially numbered, (3) the system should be computerized, (4) identification of the patient, and (5) adequate follow-up investigation of the intelligence disclosed by the system.

Triplicate prescription programs provide several advantages: (1) reduce forgeries, (2) provide a means for detecting forgeries promptly for purpose of subsequent investigation, (3) deter the physician who might prescribe excessive quantities, and (4) detect the physician who is prescribing large quantities, the pharmacy which is dispensing many prescription orders, and the *"patient"* who is obtaining excessive supplies of drugs.

There are other advantages to triplicate prescription programs. These include: (1) prevents physician from becoming unknowingly a supplier of controlled substances to addicts, (2) provides physician with a ready-made record of controlled substances prescribed, and (3) serves as a law enforcement tool providing vital information needed to initiate an investigation.

Standards of Practice

A number of guidelines have been prepared to give guidance to professionals and to establish acceptable professional responses to the demands of the Controlled Substances Act. Examples of such guidelines include the AMA prescribing guidelines for barbiturates and barbiturate-like drugs. Similarly, the Harris County Medical Society (Texas) prepared guidelines

for prescribing amphetamines and barbiturates. A significant step in establishing prescribing standards is the guidelines for prescribers of controlled substances prepared and approved by DEA and the national medical associations. These guidelines have received wide distribution and were published by all groups in their major publications.

In addition to the above-mentioned guidelines, a number of voluntary control programs between physicians and pharmacists to curtail abuse of amphetamines and other drugs have proven beneficial. Two such programs include the Northern Kentucky Pharmacists Association and the Jacksonville, Florida program. Both programs establish voluntary controls on the prescribing and dispensing of amphetamines and like drug products. These programs place self-imposed, strict professional controls on the physician and the pharmacist. For example, the Kentucky policy on amphetamines and some other Schedule II preparations requires the following:

- No inventory of amphetamines or Schedule II diet medications is to be stocked in any pharmacy.
- No prescription orders of the above drugs are to be dispensed without prior arrangement between physician and pharmacist.
- Physicians are encouraged, when prescribing for special situations as narcolepsy, hyperkinesis, and neurotic fatigue, that either the diagnosis or the message "phone me if necessary" be written on the prescription order.
- Quantity prescribed should be only in original container amounts and the patient informed that the pharmacist may need two or three days to order the medication.

The first state medical examining board to take action to control amphetamine was Wisconsin. Late in 1977 the medical examining board promulgated an administrative rule under the State Medical Practice Act which in effect made the use of amphetamines and phenmetrazine in the treatment of obesity unprofessional conduct. The rule lists seven legitimate uses: treatment of narcolepsy; hyperkinesis; drug-induced brain dysfunction; epilepsy; depression shown to be refractory to other therapeutic modalities; the differential diagnostic psychiatric evaluation of depression; or the clinical investigation of the effects of such drugs. The initial administrative rule restricted all anorectic drugs in Schedules II, III, and IV. The final rule was amended to apply only to Schedule II drugs.

Another state, Arkansas, recognizing the need to place professional controls on amphetamine adopted the following regulation which is printed in full.

REGULATION NO. 7
Regulations Governing the Prescribing of Amphetamines and Amphetamine-Type Drugs

All prescriptions for amphetamine and Schedule II amphetamine-type drugs (controlled substances) must comply with both state and Federal laws and, in addition, must contain an indication by the physician writing the prescription of the physical or mental condition of the patient which indicated the prescription.

Prescriptions for amphetamine and Schedule II amphetamine-type controlled substances may be written by a physician only for the treatment of narcolepsy or hyperkinesis. No second or subsequent amphetamine prescription may be written for the patient nor may a refill be authorized until a second opinion is obtained from a physician confirming (1) the diagnosis of narcolepsy and (2) that the amphetamine-type drug is the drug of choice. Violation of this regulation shall constitute grossly negligent or ignorant malpractice and shall subject the physician to all penalties provided in **Ark State. Ann. S72-613.**

Another set of standards is the guidelines for institutional use of controlled substances of the American Society of Hospital Pharmacists. Still another example of voluntary guidelines is the National Wholesale Druggists' Association's *"Controlled Substances Compliance Manual."*

Prescription Forgeries

Another area which is the cause of constant concern to DEA is the problem of the diversion of legitimately manufactured drugs. Repeatedly, state and local law enforcement agencies, as well as pharmaceutical industry representatives, cite prescription fraud as a substantial part of this problem. The DEA recognizes that attempts to obtain legitimately manufactured controlled drugs by misrepresentation — i.e., forged prescription orders and stolen prescription blanks — are significant problems confronting physicians, pharmacists, and local law enforcement agencies.

Realizing the need to provide professional guidance to deter efforts by forgers, a number of programs have been established for alerting pharmacists of possible prescription forgeries. The programs generally provide for a rapid communication system from pharmacy to pharmacy—to other health professionals—to DEA—to state/local law enforcement agencies. Two systems which are noteworthy to mention are the **Erie County Rx Forge Alert System** (Pennsylvania) and **Denver Pharm-Alert System.** Also, the Nevada Pharmacists Guild has a similar system which they call their **Prescription Fraud Hotline.** All these systems involve a telephone relay system to pass and obtain timely information.

Communication Is Important

Many state licensing boards have provisions in the state practice acts to disseminate information to licensees. But, the states usually do not provide funds to print or mail the information. In an effort to encourage state pharmacy boards to issue newsletters and to strengthen board of pharmacy-to-practitioner communications, a number of state pharmacy boards, in conjunction with the National Association of Boards of Pharmacy, have joined to publish a State Board Newsletter. These newsletters promote voluntary compliance of pharmacy and drug laws. The newsletters are sent to every licensed pharmacist in that respective state. The primary goal is to improve communication and compliance. The newsletter provides current information on Federal and state laws and gives guidance to pharmacists for compliance. Hopefully, licensing boards in the other professions will seek and obtain the necessary support and funds to keep their licensees informed. One area which has been a successful deterrent to errant practitioners is the mere publication of the names of violators in the state newsletters. This practice is a very effective tool to deter them from future such actions. Consequently, this practice is encouraged.

What Can We Do?

There are many programs which have not been written about. But, the value of the professions reaching out to impose stricter standards than are required by the law or regulations cannot be underestimated. All regulatory bodies should give their full support to encourage self-regulation.

Professional groups and licensing boards have taken some steps to go beyond the existing law and regulations. The willingness of the professions to take their own action to control the drug problem is commendable. □

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